ABLE MEDICAL

Valkyrie® Thoracic Fixation System

December 2023
Able Medical Devices
For Symbols Glossary, please see the end of this document.

INSTRUCTION FOR USE

IMPORTANT

This information is intended to aid in using this system and is not a reference for surgical technique. Refer to the surgical technique manual for instructions for proper implantation and removal, including selection of suitable implant sizes, accessories, and related devices, and ways to avoid or minimize risks associated with implantation.

DESCRIPTION

The Valkyrie Thoracic Fixation System includes plates and screws in a variety of configurations used to temporarily fixate fractured bone during healing. Plates are comprised of PEEK; screws are comprised of Titanium Alloy with or without Hydroxyapatite surface treatment. The system also includes instruments necessary for the insertion of the device. When used for sternal closure, The Valkyrie Thoracic Fixation System may be used with or without traditional cerclage (wire or cable).

INDICATIONS FOR USE

The Valkyrie Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies. The system is intended for use in patients with normal and/or poor bone quality.

CONTRAINDICATIONS

Contraindications for this system are active or latent infection, sepsis, insufficient quantity or quality of bone/soft tissue, and material sensitivity. If metal sensitivity is suspected, tests should be performed prior to implantation.

Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for this device.

WARNINGS

- For safe and effective use of this implant, the surgeon must be thoroughly familiar with the implant, the methods of application, the instruments, and the recommended surgical technique for this device.
- Surgeons must carefully consider the likelihood of tissue healing being achieved when plating fractures, osteotomies, or reconstructions of the chest wall. This system is only designed to withstand loading during a reasonable healing time period and is not intended to be a permanent tissue replacement.
- Confirm screws are fully seated within the plate and construct is properly seated onto bone. Improper insertion of the device during implantation can increase the possibility of loosening or migration.
- Device damage or breakage can occur when the implant is subjected to increased loading associated with trauma, delayed union, nonunion or incomplete healing. Device breakage in such circumstances is expected and could lead to additional surgery and device removal.
- The patient must be cautioned about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or unwanted outcomes as a result of loose fixation and/or loosening, stress, excessive activity, or continuous load bearing past the average healing time (6-8 weeks), particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete bone healing.
- The patient must be warned that failure to follow postoperative care instructions can cause the implant and/or treatment to fail, including fracture of the device and/or migration.
- As with any surgical implantation there is a possibility of nerve, bone or soft tissue damage related to either trauma associated with surgery or the individual patient response to the presence of the implant.

PRECAUTIONS

All implants and instruments are single-use only.

  - o An implant shall never be reused. Previous stresses may have created imperfections which can lead to a device fracture.
  - o Sterile instruments shall never be reused. Previous stresses may have created imperfections which may lead to instrument wear or fracture, preventing use as intended.

- Extreme or repeated bending or contouring of the implants can cause stresses that may lead to premature device fracture.
- Visually inspect implants for damage prior to installation; use of a damaged implant may lead to device fracture.
- Use of instruments other than what is recommended in the surgical technique may result in the construct not functioning as intended.
- If cutting the plate, take necessary precautions as a sharp edge may have been created.
- During use of a driver, cutting or installing plates and inserting screws, take necessary precautions when in close proximity to sharp edges and points, and be aware that debris/fragments can be generated. Remove any observed debris/fragments from the surgical field with suction or manually, and dispose of appropriately.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

ADVERSE EFFECTS

Possible adverse effects include:

- Pain, discomfort, or abnormal sensations due to the presence of an implant.
- Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device.
- Implant fracture, nonunion, delayed union, migration and/or loosening may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. These types of adverse effects could lead to additional surgery and device removal. Selection of screws which are longer than the depth of the sternum may cause possible impingement of structures internal to chest wall including vessels, pleura and other structures, leading to perforation of the vessels and/or blood loss.
- Formation of seromas
- Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate/incomplete healing may result from the presence of an implant or due to surgical trauma.
- A histological or allergic reaction resulting from the implantation of a foreign material in the body may occur.
- The implant contains metal that may induce an allergic reaction in patients with an allergy or sensitivity to metallic components.
- Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

MRI Safety Information:

The Valkyrie Thoracic Fixation System is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field	1.5 T or 3.0 T
Maximum magnetic field spatial gradient	20 T/m (2,000 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no RF Transmit Coil restrictions.
Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode
Maximum Whole Body Averaged SAR	2 W/kg
Maximum Scan Duration	60 minutes

The presence of this implant may produce an image artifact.

STERILIZATION

Sterilized by irradiation. Do not use if package is open or damaged. Do not re-sterilize. This is a single use device. Products intended for single-use must not be re-used in a subsequent procedure. Re-use or reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death. Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

PACKAGING AND STORAGE

The devices are packed in protective packaging that is labeled to its contents. All implants and instruments are supplied sterile. Always store the devices in the original protective packaging. Store the devices in a dry and dust-free place (standard medical device storage and hospital environment).

MAINTENANCE, INSPECTION, AND TESTING

Before use, inspect the implant/instrument box carefully. Do not use when sterile barrier is visually damaged; return immediately to manufacturer. Do not use expired product.

MANUFACTURER CONTACT INFORMATION

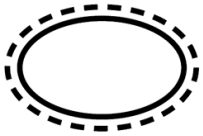
Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

MANUFACTURER CONTACT:	**PHONE: (906) 201-5323** **WEBSITE: www.ablemedicaldevices.com**
Manufacturer Address **ABLE MEDICAL DEVICES:**	**512 4th Street, Gwinn, MI 49841**

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD TITLE	STANDARD; REFERENCE NUMBER
	Manufacturer	Indicates the medical device manufacturer.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223-1; #5.1.1
			Graphical symbols for use on equipment	ISO 7000; #3082
	Date of Manufacture	Indicates the date when the medical device was manufactured.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223-1; #5.1.3
			Graphical symbols for use on equipment	ISO 7000; #2497
	Use by Date	Indicates the date after which the medical device is not to be used.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223.1; #5.1.4
			Graphical symbols for use on equipment	ISO 7000; #2607
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223.1; #5.1.5
			Graphical symbols for use on equipment	ISO 7000; #2492
	Catalog Number	Indicates the manufacturer's catalog number so that the	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied	ISO 15223.1; #5.1.6

		medical device can be identified.	– Part 1: General requirements	
			Graphical symbols for use on equipment	ISO 7000; #2493
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223.1; #5.2.4
			Graphical symbols for use on equipment	ISO 7000; #2502
	Do not resterilize	Indicates a medical device that is not to be resterilized.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223.1; #5.2.6
			Graphical symbols for use on equipment	ISO 7000; #2608
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223.1; #5.2.8
			Graphical symbols for use on equipment	ISO 7000; #2606
	Do not re-use	Indicates the medical device is intended for one single use only.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223-1; #5.4.2
			Graphical symbols for use on equipment	ISO 7000; #1051
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223-1; #5.4.3
			Graphical symbols for use on equipment	ISO 7000; #1641
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223-1; #5.4.4
			Graphical symbols for use on equipment	ISO 7000; #0434

	Prescription only	The symbol for Prescription Device. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	NA	Reference: 21 CFR Part 801.15(c)(1)(i)F 21 CFR Part 801.109(b)(1)
	Quantity	Indicated the number of units per package	NA	NA
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields.	ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	NA
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements	ISO 15223- 1 ; #5.2.14
			Graphical symbols for use on equipment	ISO 7000; #3709